However, VAERS is a passive surveillance system that generally cannot address, in a scientifically valid manner, the critical question of whether the administration of a vaccine causes an adverse event. One way to address this question of causation is through the use of large, linked data bases (LLDBs), such as those at the CDC, in which computerized vaccination records are linked with computerized medical records to assess linkages between health status and prior vaccination. These data bases represent a unique resource for the systematic and timely postlicensure evaluation of vaccine safety. Epidemiological studies are another mechanism for evaluating whether vaccines may or may not be the cause of a particular adverse event. Such studies are generally performed on an ad hoc basis when surveillance or other sources of data suggest the possibility of a causal association.

In response to concerns regarding vaccine safety and appropriate compensation for those who suffer adverse consequences from vaccinations, Congress created the National Vaccine Injury Compensation Program (NVICP) in 1986 through P.L. 99-660. In addition, this legislation mandated reviews of adverse consequences of pertussis and rubella vaccines (section 312) and other vaccines (section 313). The results of those reviews have now been published (Institute of Medicine, 1991, 1993). They suggest that for many of the allegedly vaccine-related adverse events reviewed, the scientific evidence was inadequate to accept or reject a causal association. They also provide several suggestions for improving scientific understanding of vaccine-related adverse events.

P.L. 99-660 also mandated the creation of the Task Force on Safer Childhood Vaccines. The task force anticipates publication of its conclusions and recommendations in a report scheduled for completion in 1994.

Efforts to ensure vaccine safety and public confidence in vaccination are continuously monitored by the National Vaccine Program Office and other agencies and are modified as necessary in the light of the best information available. As of January 1994, comprehensive reviews are being conducted of product labeling, the vaccine information pamphlets on the vaccines required for school entry, the system for identifying vaccine-related adverse events, and the NVICP Vaccine Injury Table that defines compensable events. To improve on present levels of vaccine safety, and to maintain pubic confidence and participation in vaccination, expanded research on efficacy and safety issues will be needed to guide future regulatory decisions and for use in developing recommendations on vaccine use.